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by the sensor at an intermediate site of said tube arrangement, the body fluid being aspirated to said intermediate site.



Remarks

The above amendments and these remarks are being submitted with a Request for Continued Examination under 37 CFR § 1.114, and in response to the Office Action of August 29, 2000.

In view of the above amendments and these remarks, the rejections in the Office Action are respectfully traversed, and reconsideration is requested.

Claims 1-4, 6, 8, 10-13, and 15-19, 21 and 23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by US Patent 5,281,199 (Ensminger), and claims 1-24 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Ensminger in view of US Patent 5,607,390 (Patsalos).

§102 Rejection

Basically, the Examiner maintained the §102 rejection of the first Office Action asserting, accurately, that Ensminger discloses a self sealing diaphragm teaching “leaflet valve elements 38 and 40 to reseal...”. (Office Action of August 29, page 2, paragraph 2, lines 9-10.)

By the above amendments, claims 1-9, 11 and 19 have been canceled, obviating the § 102 rejection thereof. Claims 10 and 16 have been amended to include the element of an “elastic” self sealing diaphragm.

In contrast, and as pointed out by the Examiner, the Ensminger patent discloses a valve system using a multi-element leaflet valve assembly. (Ensminger, page 9, lines 60-61.) A valve system

comprising an elastic self closing diaphragm, such as that of the present invention, is not disclosed or taught in the patent. For at least this reason, claims 10 and 16, as amended, are not anticipated by Ensminger.

Dependent claims 12-15, 21 and 22 depend directly or indirectly from amended claim 10 and are allowable over Ensminger for the same reason. Claims 17, 18, 23 and 24 depend from amended claim 16 and are allowable over Ensminger for the same reason.

§103 Rejection

Basically, the Examiner maintained the rejection from the first Office Action, asserting that claims 1-24 are obvious under §103(a) over Ensminger in view of Patsalos.

It is respectfully submitted that the claims are not obvious over Ensminger in view of Patsalos. Notwithstanding the Examiner's comments and citing of cases, a rejection cannot be based on surmise, and the Examiner has not pointed to any objective evidence establishing what he considers knowledge generally available to one skilled in the art. Second, Ensminger teaches away from the present invention, and third, it would be functionally impossible to modify the Ensminger device, whether in view of Patsalos or not, to achieve the present invention as claimed in the amended claims. Even if the asserted combination were proper, it would fail to teach applicant's invention because it would not disclose or teach a device or method for detecting the concentration and/or existence of substances in body fluids as claimed in the amended claims, i.e., using an elastic self closing diaphragm.

As discussed above, the Ensminger patent discloses and teaches only a multi element leaflet valve assembly for use in the valve chamber, whereas amended claims 10 and 16 recite an elastic self closing diaphragm. Thus, the Ensminger invention teaches away from the present invention.

Further, the Ensminger patent discloses a “needle stop” feature in the passageway. (Ensminger, page 9, lines 65-67.) This feature is a bend in the shaft which prevents a needle or any other sharp rigid accessing instrument from entering the valve assembly of the invention so as to not puncture the valve assembly. (Ensminger, page 8, lines 9-12.) In contrast, the elastic self closing diaphragm of the present invention is meant to be punctured by sharp accessing instruments. Clearly, one skilled in the art would not look to the Ensminger patent for a disclosure or teaching about elastic self closing diaphragms.

The Examiner suggests that it would be obvious to one of ordinary skill in the art to use Patsalos et al’s microdialysis probe in combination with Ensminger et al’s access device for analyzing body fluids, but even if so, the combination would fail to disclose or teach applicant’s invention as claimed in the amended claims, namely, it would not disclose or teach a device for detecting the concentration and/or existence of substances in body fluids comprising an access means with an elastic self closing diaphragm for accessing the interior of the body, wherein the access means is implantable in the body and adapted to allow access to the body fluids through the diaphragm as recited in amended claims 10 and 16.

Dependent claims 21-24 are directed to the anchor of the present invention and it appears that the Examiner has failed to appreciate the differences between the present invention and the Ensminger device. Ensminger discloses a base section that is sutured or stapled to supporting tissue. The

Ensminger device is quite bulky and heavy compared to the present invention, and thus requires more support (in the form of sutures or staples) to stabilize and anchor it. An advantage of the anchoring system of the present invention is that it does not require sutures or staples, and thus eliminates the risk of infection resulting from the use of them.

For at least the preceding reasons, it is submitted that the present invention is not obvious over Ensminger in view of Patsalos.

New Claims

New claims 25 and 26 have been added. These claims recite that the device of the present invention comprises a tube arrangement comprising an intermediate site for receiving a test sensor and for receiving body fluids aspirated toward said site. This feature is not disclosed or suggested by either patent cited by the Examiner and, advantageously, provides for reducing the negative influence of possible deposits at the ends of the tube arrangement, possible contamination and temperature fluctuations. (See the present specification, page 5, line 19-page 6, line 2, and original claim 7.)

Fees

It is believed that no claim fees should be due in connection with this submission; however, the Office is hereby authorized to charge any deficiency, or credit any overpayment associated with this submission, or the accompanying Request for Continued Examination, to Deposit Account 04-1420.

A check in the amount of \$1600.00 is enclosed (\$710.00 of which is to cover the RCE fee and \$890.00 of which is to cover the three-month extension fee).

Conclusion

In view of the above amendments and preceding remarks, it is urged respectfully that the rejection of the remaining claims be reconsidered, and that they be allowed, along with the new claims. If the Examiner believes that it would be helpful, he is invited to telephone the undersigned.

Respectfully submitted,

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